

Holtec International: Cask Change Control and Corrective Action Concerns

November 2021

The U.S. Nuclear Regulatory Commission (NRC) issued federal regulations (10 CFR Part 72) in August 1988 governing storage of spent fuel following its removal from a nuclear reactor core and its transport to a reprocessing facility or repository. The regulations include provisions applicable to the manufacturers of dry cask storage systems and to the users of these systems. Two of the provisions:

Change Control: The Nuclear Energy Institute (NEI), a nuclear industry trade organization, developed a guidance document to help manufacturers and users implement the change control regulatory requirements. NEI explained the role of these requirements:

10 CFR 72.48 establishes the conditions under which an independent spent fuel storage installation (ISFSI) licensee, a monitored retrievable storage installation (MRS) licensee, or a spent fuel storage cask certificate holder may make changes to the ISFSI facility, MRS, spent fuel storage cask design, or procedures; and conduct tests or experiments, without prior NRC approval. Proposed activities that satisfy the definition of change, test, or experiment included herein and meet one or more of the criteria in the rule must be reviewed and approved by the NRC before implementation. Thus, 10 CFR 72.48 provides a threshold for regulatory review—not the final determination of safety—for proposed activities.¹

Prior NRC approval is required when a proposed change:

- (i) Results in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the Final Safety Analysis Report (FSAR);
- (ii) Results in more than a minimal increase in the likelihood of occurrence of a malfunction of a system, structure, or component (SSC) important to safety previously evaluated in the FSAR;
- (iii) Results in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR;
- (iv) Results in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR;
- (v) Creates a possibility for an accident of a different type than any previously evaluated in the FSAR;
- (vi) Creates a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the FSAR;
- (vii) Results in a design basis limit for a fission product barrier as described in the FSAR being exceeded or altered; or
- (viii) Results in a departure from a method of evaluation described in the FSAR used in establishing the design bases or in the safety analyses.

Section 72.48 allows cask manufacturers and users to make changes on their own as long as the safety boundaries established by the NRC's prior approvals are not compromised or the methods

¹ Nuclear Energy Institute 12-04, Rev. 1, Draft A, Guidelines for 10 CFR 72.48 Implementation, September 2017, page 1. (ML17249A095)

reviewed by the NRC to chart those boundaries are not altered. Otherwise, the proposed change must be submitted to the NRC for its review and approval before being implemented.

Corrective Actions: The spent fuel storage regulations adopted by the NRC recognized that problems will arise and 72.172 require that cask manufacturers and users:

*... establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances, are promptly identified and corrected. In the case of a significant condition identified as adverse to quality, the measures must ensure that the cause of the condition is determined and corrective action is taken to preclude repetition.*²

Section 72.172 requires that safety problems be found and fixed in a timely and effective fashion. Doing so preserves the safety margins established by the NRC's approval; failing to do so erodes the safety margins.

Holtec International is a manufacturer of dry casks. At certain nuclear plants, including Indian Point in New York, Oyster Creek in New Jersey, and Pilgrim in Massachusetts, Holtec is also the dry cask user.

For over the past ten years, Holtec has experienced numerous problems complying with the change control (72.48) and corrective action (72.172) federal regulations. The sustained occurrences of these regulatory violations, and their associated adverse safety implications, are troubling. The next two sections detail the change control and corrective action violations NRC has issued to Holtec dating back to 2009.

² *Federal Register*, Vol. 53, No.161, August 19, 1988, page 31677.

Cask Change Control Violations

On October 28, 2021, the NRC issued a report on its inspection of Holtec's cask manufacturing facility. The report documented three violations of 10 CFR 72.48:

- *Holtec did not correctly conclude that a change did not affect the technical specification incorporated in the CoC [Certificate of Compliance] for specified requirements associated with one of the transfer casks the HI-TRAC 100G associated with the HI-STORM 100 cask system;*
- *Holtec did not include a complete written evaluation which provided the bases for the determination that the addition of a Girdle Beam Structure (GBS) on the HI-STORM 100 overpack, Version B, did not require a license or CoC amendment. Specifically, Holtec did not subject design changes to design control measures commensurate with those applied to the original design in that the written evaluation did not consider the critical stresses and strains that the GBS would place on the overpack, canister, and fuel basket; and*
- *Holtec did not include a complete written evaluation which provided the bases for the determination that the change that incorporated a new overpack and lid designated as the version (E) for HI-STORM Flood and Wind (FW) cask system did not determine require a CoC amendment, which may have met one or more of the 10 CFR 72.48 criteria, which may require prior NRC review and approval before the implementation.³*

The violation involving the HI-TRAC 100G cask were new administrative controls implemented without NRC's approval that would allow the cask to be moved without using single-failure proof lifting equipment. Unlike for its other casks, Holtec had not analyzed the HI-TRAC 100G for a side drop accident because it determined that a drop could not happen because "... the HI-TRAC 100G will always be handled by a single failure-proof lifting equipment."⁴ The NRC did not accept that assertion.

The NRC reviewed 15 screenings and 20 evaluations conducted by Holtec per 10 CFR 72.48. Thus, the NRC found fault with 8.6% of the 72.48 documents it reviewed.⁵ If the NRC reviewed a representative sampling, it means that 8.6% of the screenings and evaluations not reviewed by the NRC were also deficient.

The NRC's inspection report identified a weakness in Holtec's 72.48 process that may contribute to the recurring violations:

The team also noted that Holtec used canned responses to evaluate the eight criteria questions under 10 CFR 72.48(c)(2), which sometime did not address or capture the specific design change. For example, the canned response for criterion seven related to design basis limits for a fission product barrier sometimes focused only on the maximum peak cladding temperature design basis limit. However, there are other parameters that may impact the fission product barrier such as decay heat, and the number of thermal cycles. Additionally, the team noted that the confinement barrier may also be impacted such as allowable stresses, or max deceleration or g-loads on the canister or fuel basket. The team noted that the canned response may limit the evaluator responses to the actual design change.⁶

³ NRC Inspection Report No. 72-1014/2021-201, October 28, 2021, enclosure page 2. (ML21301A166)

⁴ NRC Inspection Report No. 72-1014/2021-201, October 28, 2021, enclosure page 12. (ML21301A166)

⁵ NRC Inspection Report No. 72-1014/2021-201, October 28, 2021, enclosure page 12. (ML21301A166)

⁶ NRC Inspection Report No. 72-1014/2021-201, October 28, 2021, enclosure page 16. (ML21301A166)

It is not sufficient to have all the right answers unless all the right questions have been asked. The NRC found that key safety questions may not be answered by Holtec's 72.48 process. Considering that Holtec has re-tooled its 72.48 process time and again over the past decade in response to NRC 72.48 violation after 72.48 violation, it is very hard to understand how NRC could find it so lacking in late 2021.

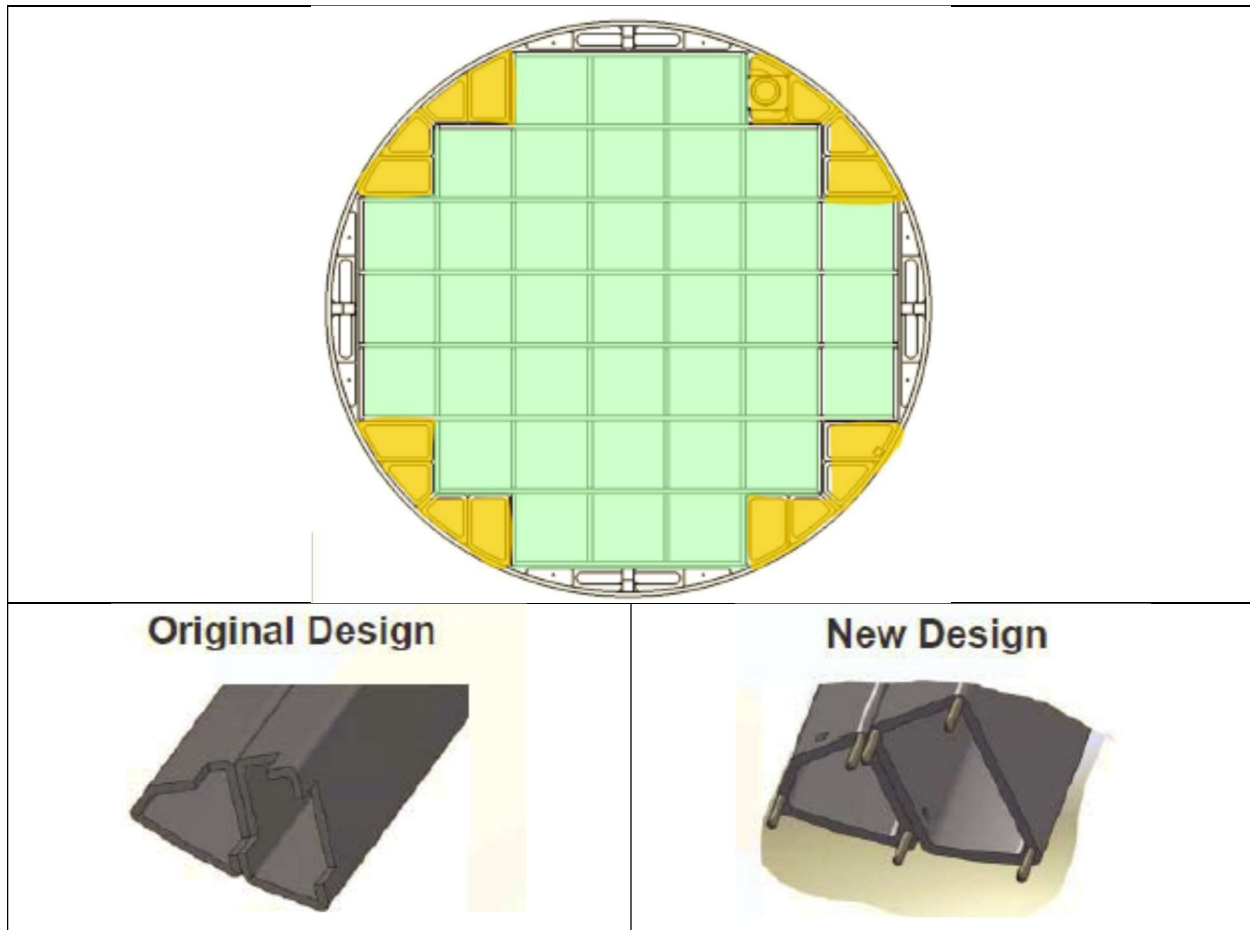
Two years earlier, the NRC issued a 72.48 violation for unapproved changes to the criteria for determining when scratches and gouges in canister outer surfaces are acceptable following an event in 2018 at San Onofre in California. The NRC reported:

*The NRC reviewed a sample of 72.48's and noted Holtec performed two separate canister scratch/gouge 72.48 evaluations, one to address the 5/8-inch thick shell wall (72-1384, Revision 1) and the other to address the 1/2-inch thick shell wall (72.48 -1357, Draft Revision 3) canister configurations. Both configurations are applicable to the HI-STORM UMAX canister storage system and both 72.48 evaluations concluded that the scratch/wear potential from downloading would result in local structural discontinuities as peak stresses. **The NRC noted the evaluations failed to demonstrate an estimation of gouge sizes was achieved through any identified methodology and that no evaluation was provided to compare the estimated gouge sizes to acceptance criteria for minimum wall thickness, as identified in the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, Section III (or Section XI).** The current regulatory compliance is that the MPC meet ASME Section III. According to Holtec, the applicable stress intensity limits of ASME Section III for pressure retaining boundary are unaffected by the presence of scratches and defaulted to minimum wall thickness to meet the design internal pressure for the canister as 0.216" (per NB-3324 of the ASME Code); leaving a substantial thickness reserve (> 0.25 ") for imperfections such as scratches. However, **the NRC noted absence of a technical basis and analysis in support of this conclusion.** The NRC assessed that this was a violation of NRC requirements related to 10 CFR 72.48(d)(1). [boldfacing added for emphasis]*⁷

A few months earlier in 2019, the NRC issued another violation of 72.48 for unapproved changes identified during the receipt inspection of another cask at San Onofre in California. The NRC reported that Holtec modified the design of shims installed within spent fuel canisters in August 2016. The shims (shaded in yellow in the top graphic below) are inserted in the irregular shaped spaces between the cylindrical canister and the square-edged baskets holding fuel assemblies.⁸

⁷ NRC Inspection Report, August 16, 2019, enclosure page 7. (ML19228A016)

⁸ NRC Inspection Report, November 29, 2018. (ML18306A853)



Source: Holtec International Slides for NRC Pre-Enforcement Conference, January 9, 2019 (revised January 11, 2019). (ML19015A118)

In the original shim design, rectangular regions of the bottom edges were machined away to provide pathways for the inert gas within a loaded canister to circulate and aid in transferring the decay heat generated by spent fuel assemblies out of the canister.

In the modified design, stainless steel pins were inserted in the flat bottom edges of the shims to provide “legs” that created the same gas flow pathway.

In February 2018, workers at the San Onofre nuclear plant in California identified a broken shim pin. The NRC’s ensuing investigation concluded that Holtec improperly revised the shim design without first obtaining the NRC’s approval:

NRC staff reviewed the Holtec analysis and concluded that the heat transfer characteristics of the MPCs [multi-purpose canisters] were adequate and that loaded MPCs would continue to be in a safe condition during the entire licensed period of storage as described in the respective CoC [Certificate of Compliance]. As a result of this review, the NRC determined that Holtec’s violation of 10 CFR 72.48 and 10 CFR 72.146 did not result in an actual significant safety concern. However, the NRC considers Violation 1 to be of moderate safety significance because Holtec’s inadequate design control measures did not adequately assess a potentially credible accident and exposure scenario that had the potential for a significant consequence. The failure

*of multiple stand-off pins in an MPC could have resulted in inadequate heat transfer and the exceedance of peak clad temperature limits. [boldfacing added for emphasis]*⁹

On November 29, 2018, the NRC reported three 72.48 violations from its review of twenty-three 72.48 documents. If the NRC reviewed a representative sampling, it means that 13% of the screenings and evaluations not reviewed by the NRC were also deficient. One of the 72.48 violations was the shim pin issue described above. The other two 72.48 violations cited by the NRC were:

- Holtec modified the HI-TRAC VW transfer cask design to include an air inlet in the bottom lid. This added vent requires continuous monitoring by workers to guard against cooling flow blockage. Holtec's evaluation deemed that inlet blockage was non-credible because workers would not leave a loaded cask unattended. The NRC disagreed with that position and noted that it also contradicted the guidance established by NEI:

*The response from Holtec did not agree with the guidance in NEI 96-07 Appendix B (as endorsed by RG 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments"). For example, NEI 96-07 Appendix B 4.3, states, in part, that an increase in frequency or likelihood of occurrence cannot be compensated for by additional mitigating actions (i.e., operator actions). ... The team determined that the requirement for an operator to be continuously present and to verify that vents remained free of debris would meet the more than minimal increase in the likelihood of occurrence of a malfunction (e.g., human performance errors). The change also would affect the technical specifications in that it would require an additional surveillance requirement to verify inlet and outlet vents are free of blockage and administrative controls for new surface does rates for the HI-TRAC.*¹⁰

- Holtec reduced one of four lift cleat studs on a multi-purpose canister at Pilgrim on January 21, 2015, due to a damaged lifting hole. The NRC cited Holtec for failing to obtain a license amendment for removal of one of four lift cleat studs. The removal "created a possibility for a malfunction of a different result than any previously analyzed" according to the NRC.¹¹

The NRC issued a 72.48 violation to Holtec on February 24, 2011, for an unacceptable evaluation of spent fuel integrity following a design basis cask drop:

The team noted that the 72.48 change: a) introduced a completely new method as the basis for demonstrating the integrity of the fuel rod cladding during a vertical end drop of the HI-STORM 100 while being transported to the ISFSI pad.

The team determined that 72.48 Evaluation No. 923 resulted in a change that is a departure from a method of evaluation described in the FSAR used to establish the safety analysis for cladding integrity during a drop accident event. This failure to comply with the requirements of 10 CFR 72.48(C)(2), (viii) which states, "a certificate holder shall obtain a CoC amendment pursuant to 72.244 prior to implementing a proposed change, if the change would result in a departure from

⁹ NRC Inspection Report and Notice of Violation, April 24, 2019, page 2. (ML19072A128)

¹⁰ NRC Inspection Report, November 29, 2018, enclosure page 15. (ML18306A853)

¹¹ NRC Inspection Report, November 29, 2018, enclosure page 17. (ML18306A853)

*a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses,” is cited in the attached Notice.*¹²

The NRC issued a 72.48 violation on August 5, 2009, for Holtec’s unapproved elimination of a leaktightness check. Before the elimination, casks were pressure tested using helium gas to demonstrate that the multi-purpose canister shell and baseplate welds were leaktight. The NRC concluded that elimination of the leak test had not been adequately evaluated:

*The NRC determined that none of the reasons provided by Holtec in the evaluation were adequate to demonstrate the leaktightness of the MPC. These new evaluation methods have not been previously approved by NRC, as a basis for demonstrating confinement integrity. Specifically, the non-destructive examinations (i.e., a radiographic examination and a surface liquid penetrant examination) performed during the fabrication of the MPC are designed to detect the presence of weld flaws above a threshold size to demonstrate that structural integrity can be maintained. However, these examinations are not intended to demonstrate that the MPC welds can prevent helium leakage to the small values necessary to demonstrate leaktightness. ... Finally, Holtec’s theoretical model was not considered bounding since it predicted the helium leakage through micro-capillary sized flaws that are orders of magnitude smaller than the flaw detection limits achievable by the non-destructive examination methods used during the fabrication of MPCs.*¹³

The NRC explained the safety significance of the violation:

This issue is considered to be of greater than minor significance since approximately 120 MPCs were loaded without being adequately tested to demonstrate their leaktightness. Leaktightness is required for the HISTORM 100 System to ensure radiological confinement and also to ensure that adequate helium overpressure is retained to ensure adequate cooling of fuel stored in the MPC. [boldfacing added for emphasis]¹⁴

The next section describes corrective action violations issued to Holtec by the NRC.

¹² NRC Inspection Report, February 24, 2011, enclosure page 8. (ML110450157)

¹³ NRC Exercise of Enforcement Discretion – Holtec International, August 5, 2009, enclosure page 1. (ML092180140)

¹⁴ NRC Exercise of Enforcement Discretion – Holtec International, August 5, 2009, enclosure page 2. (ML092180140)

Cask Corrective Action Violations

On February 24, 2021, a worker received an internal radiation dose when radioactively contaminated water sprayed from a dry cask being pressure tested at the Oyster Creek nuclear plant in New Jersey. The leaked water contaminated the work platform around the cask as well as the 23-foot and 51-foot levels (floors) of the reactor building. The NRC reported:

During performance of the test, the RVOA [Removable Valve Operating Assembly] was connected by two snap rings to a spring collar assembly attached to the vent port on the lid of the MPC [multi-purpose canister]. During this particular evolution, the licensee determined that the snap rings failed during hydrostatic testing causing the RVOA to abruptly become disengaged from the spring collar, which remained attached to the MPC vent port. Contaminated water exited the MPC vent port.¹⁵

The NRC stated that RVOA snap ring problems had been experienced during prior cask loadings at Pilgrim since December 2020, but those problems had neither been entered into the corrective action program nor remedied:

10 CFR Part 72.172 “Corrective Action” requires in part that, “the licensee and certificate holder shall establish measures to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective materials and equipment, and nonconformances, are promptly identified and corrected.”

Contrary to the above, from December 14, 2020 to February 24, 2021, the licensee failed to identify and correct a condition adverse to quality. Specifically, the licensee failed to ensure that bending of the snap rings were promptly identified and placed in the CAP. This resulted in the failure of the snap rings during hydrostatic testing on February 24, 2021.¹⁶

On March 18, 2000, the NRC informed Holtec that its corrective actions for a violation of 72.48 was inadequate:

This letter refers to the U.S. Nuclear Regulatory Commission’s (NRC’s) in-office review of your response to a Notice of Violation (NOV) (NRC’s Agencywide Documents Access and Management System Accession No. ML19242B835). The NOV was issued for failure to conduct an adequate evaluation in accordance with 10 CFR 72.48 prior to making proposed design changes (ADAMS Accession No. ML19228A016).

On August 28, 2019, you responded to the NOV. The NRC has found your response inadequate, in that, the corrective actions you took in response to the violation, your analysis that serves as part of the basis for your 72.48 evaluation, did not fully address the violation.¹⁷

In a similar hybrid of a 72.48/72.172 violation, the NRC reported that Holtec workers failed to measure the length of fuel baskets before installing them in numerous multi-purpose canisters. When this oversight was detected, Holtec merely dispositioned the matter as “accept-as-is.” The NRC determined:

... that Holtec needed to perform a 72.48 screening/evaluation as described in Section 6.2.3.4 of HQP-15.2 [Holtec’s quality assurance procedure]. However, Holtec personnel did not perform

¹⁵ NRC Inspection Report No. 05000219/2021001, May 18, 2019, enclosure pages 3-4. (ML21132A064)

¹⁶ NRC Inspection Report No. 05000219/2021001, May 18, 2019, enclosure pages 4. (ML21132A064)

¹⁷ NRC Staff Review of Holtec International Response to the U.S. Nuclear Regulatory Commission Follow-up Inspection Report Number 07201014/2019-201, and Notice of Violation, March 18, 2000, page 1. (ML19330F234)

*the 72.48 screening/evaluation to provide the technical justification to accept the use-as-is disposition in accordance with written procedures. The team assessed that this was a violation of NRC requirements 10 CFR 72.170.*¹⁸

The next section provides conclusions and recommendations about Holtec's change control and corrective action problems.

¹⁸ NRC Inspection Report, November 14, 2017, enclosure page 3. (ML17320A387)

Cask Change Control and Corrective Action Concerns

The NRC has issued several violations to Holtec for violations of 72.172 that requires effective and timely corrective actions.

The NRC has issued more violations to Holtec for violations of 72.48 that requires changes to NRC-approved casks to be either adequately justified or pre-approved by the NRC.

In October 2021, the NRC reported violations in 8.6% of the thirty-five 72.48 documents it reviewed. In November 2018, the NRC reported violations in 13% of the twenty-three 72.48 documents it reviewed.

It is hard to put this accounting in proper context. Were 35 and 23 the entire inventories of 72.48 documents since the last NRC inspections? Or were they only fractions of the inventories?

Holtec is required to submit biennial reports to the NRC of 72.48 evaluations since the last biennial report. In its January 2014 biennial report, Holtec summarized twenty-two full 72.48 evaluations, thirty 72.48 screenings, and one revision to a prior 72.48 evaluation.¹⁹ In its biennial submittals in January 2016²⁰ and January 2019,²¹ Holtec claimed the 72.48 information was proprietary and it was withheld from public disclosure.

In any case, Holtec has recurring problems complying with the regulatory requirements governing changes to NRC-approved casks. These recurring problems are *de facto* violations of the regulatory requirements in 10 CFR 72.170 that mandate steps be taken to prevent recurrence. The record is clear that Holtec has not taken adequate corrective actions to prevent 72.48 violations; if it had, nearly 10 percent of the 72.48 documents reviewed in 2021 would NOT have resulted in violations.

The matter is far from academic. The most serious cask event in the United States, so far, was caused by 72.48 and 72.172 violations that resulted in a hydrogen burn that lifted a 2-ton lid on a loaded cask several inches. That near miss is detailed in the appendix.

72.172 requires that Holtec implement timely and effective corrective actions to fix its 72.48 shortcomings. Compliance with 72.48 is an essential element of safe dry storage of spent fuel.

¹⁹ Holtec International Biennial Report of Changes, Tests, and Experiments, January 3, 2014. (ML14007A148)

²⁰ Holtec International Biennial Report of Changes, Tests, and Experiments, January 4, 2016, page 1. (ML16004A476)

²¹ Holtec International Biennial Report of Changes, Tests, and Experiments, January 4, 2019, page 1. (ML18004A539)

Appendix - Dry Cask Hydrogen Burn Event

On May 28, 1996, workers at the Point Beach nuclear plant in Wisconsin were welding the shield lid onto a VSC-24 cask manufactured by Sierra Nevada Corporation when the welding torch ignited flammable gas inside the canister. The detonation lifted the lid, weighing more than two tons, about three inches.

Ensuing investigations determined that a Carbo Zinc II coating had been applied to the metal baskets inside the cask for holding spent fuel assemblies before loading. When the cask was lowered into the spent fuel pool for loading, an electro-chemical reaction between the coating and the borated water generated large amounts of hydrogen gas.

Prior cask loadings had revealed problems that were neither documented nor remedied. On May 22, 1996, a blue flame was noticed as workers were grinding a weld on the shield lid of another loaded cask. Also on May 22, 1996, water flowed from the drain line on top of the shield lid of yet another loaded cask, indicating some unexpected condition within the cask pressurizing its volume and forcing water out the drain line.²²

No fuel was damaged by the May 28, 1996, hydrogen burn. The NRC included the failures to adequately evaluate a change to the cask design approved by the NRC and to appropriately correct non-conforming conditions in a \$325,000 civil penalty imposed on December 3, 1996.²³

²² NRC Augmented Inspection Team Report, July 1, 1996. (ML20129G680)

²³ NRC Proposed \$325,000 Civil Penalty, EA-96-273, December 3, 1996.